PRECISION DERMATOLOGY

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2. 510(k) Summary

NOV 30 2012

2.1 510(k) Owner's Name

PreCision Dermatology, Inc.
900 Highland Corporate Drive
Cumberland, RI 02864
Device Establishment Registration Number: 3005150234

2.2 Contact Individual

Ronald M. Gurge, Ph.D.
Director, Consumer Products R&D
PreCision Dermatology, Inc.
401-762-2000, Extension 141
401-658-2167 (fax)
rgurge@precisionderm.com

2.3 Date Summary Prepared

May 25, 2011

2.4 510(k) Device Name

Proprietary Name:	HylatopicPlus® Lotion
Common/Usual Name:	Dressing, Wound & Burn, Hydrogel w/drug and/or biologic
Classification Name:	Dressing, Wound & Burn, Hydrogel w/drug and/or biologic
Panel:	General & Plastic Surgery
CFR Number:	Unclassified
Product code:	MGQ

2.5 Devices to Which New Device is Substantially Equivalent

- HylatopicPlus® Cream cleared April 1, 2011 under 510(k) K110727, from PreCision Dermatology, Inc.

2.6 Device Description

HylatopicPlus Lotion is a non-sterile, off-white, low odor, fragrance free, topical device. The HylatopicPlus Lotion forms a physical barrier that helps to maintain a moist wound and skin environment. This is a prescription device.

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2.7 Intended Use of the Device

Under the supervision of a healthcare professional, HylatopicPlus Lotion is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. HylatopicPlus Lotion also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

2.8 Device Description and Comparison

A detailed description of the proposed device and its comparison to the predicate device is located in Section 3 of this submission. Both the proposed and referenced predicate devices are oil-in-water emulsions containing humectant and emollient components which donate moisture to the skin and form a semi-permeable physical barrier on the skin. Both the predicate and proposed devices are non-sterile and are applied topically to relieve the symptoms of various dermatoses. A comparison of the intended use and labeling of the proposed and predicate device is located in Section 4 and Appendix 6. PreCision Dermatology, Inc. intends to market both the predicate and proposed devices.

2.9 Substantial Equivalence

Section 4 of this submission describes the substantial equivalence of the proposed and predicate devices in detail. In summary both devices:

- Have identical indicated uses
- Have identical operating principles
- Are both oil-in-water emulsions that are applied topically
- Contain identical device components in similar quantities (excluding preservative)
- Have identical shelf-lives
- Are manufactured by identical procedures

Therefore we believe that the HylatopicPlus Lotion is substantially equivalent to the previously cleared HylatopicPlus Cream.

900 Highland Corporate Drive · Cumberland, RI · 02864 | tel 401 762 2000 | fax 401 762 2043

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Precision Dermatology Incorporated
% Richard M. Gurge, Ph.D.
Director, Consumer Products R and D
900 Highland Corporate Drive
Cumberland, Rhode Island 02864

30 November 2012

Re: K121559
Trade/Device Name: HylatopicPlus® Lotion
Regulation Name: Unclassified
Product Code: FRO
Dated: November 15, 2012
Received: November 16, 2012

Dear Dr. Gurge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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1.7 Statement of Indications for Use

510(k) Number (if known):

Device Name: HylatopicPlus® Lotion

Indications for Use:

Under the supervision of a healthcare professional, HylatopicPlus Lotion is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. HylatopicPlus Lotion also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment. A moist wound & skin environment is known to be beneficial to the healing process.

HylatopicPlus Lotion is indicated for use in:

- Atopic Dermatitis
- Allergic Contact Dermatitis
- Radiation Dermatitis

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang

(Division Sign-Off)
Division of Surgical Devices
510(k) Number ___K121559_____